

Statement of Rep. Henry A. Waxman
Conference of the Safety Net Hospitals for Pharmaceutical Access
340B Lifetime Achievement Award

July 14, 2014

I want to thank you for having me today and thank you for this award. It is an honor to receive it.

Ted, I thank you for the warm introduction. You've done a tremendous job building the coalition in support of the 340B program, and I'm counting on your leadership to help keep the program strong.

I am proud to have been a supporter of the Safety Net Hospitals and 340B providers and the care you provide to those most in need.

Currently, California has 152 340B eligible hospitals, 167 eligible health centers, 258 eligible family planning clinics and 46 eligible Ryan White grantees. I know at least one hospital that serves Los Angeles residents, the Childrens' Hospital of Los Angeles, has a representative here today. I welcome you and thank you for your work in our community.

One of the defining goals of my career has been the expansion of health care coverage to all Americans. You and your leadership in Washington have joined me in a beneficial partnership that has lasted decades and has slowly but surely advanced that goal.

You joined me in supporting the expansion of the Medicaid program in the 1980s and 1990s. You joined me in supporting the creation and expansion of the CHiP program in the 1990s and 2000s. And you were and continue to be supporters of the Affordable Care Act.

We still have work to do – most importantly, we must make sure that the Affordable Care Act’s Medicaid expansion is extended to all 50 states – but thanks to your hard work, universal coverage is finally within our reach.

We have worked on other issues too – and one of the most important was the creation and expansion of the 340B drug discount program.

In 1992, when we created the 340B program, I worked hard to make sure that safety-net hospitals were included as covered entities.

I remember that the 340B bill that the Senate marked up was a fine piece of legislation, but it was the House Energy and Commerce Committee that added the DSH hospitals and made the 340B program such an important part of the health care safety net.

The purpose of the 340B program is twofold: (1) to help patients, and (2) to help the safety net hospitals and other providers that care for those patients

This support is critical for providers caring for large numbers of un- or underinsured patients. It was critical before we passed the Affordable Care Act – and it remains critical today – especially in states that have not expanded Medicaid or that have large numbers of residents that do not qualify for coverage under the ACA.

The increasing reports of exorbitantly high drug prices also make it important that the 340B program remain strong. I know that you are on the front lines, so you see every day the impact of these drug prices.

I have recently been particularly concerned about the impact on providers, patients, and government programs of Sovaldi, the new Hepatitis drug that costs almost \$100,000 per treatment.

The high cost of this and other Part D drugs show why we need to pass my legislation that will create a Part D rebate for drugs used by dual eligible individuals. This legislation will lower costs and save taxpayers money.

We did not get this rebate in the Affordable Care Act...but we did make a number of important improvements to the 340B program. We expanded access to the program, and we created new program compliance provisions. These new provisions were designed to address concerns raised by GAO and others about compliance by drug manufacturers and by 340B covered entities.

One key change was the enactment of new HRSA auditing requirements and new civil monetary penalties. We wanted to make sure that drug manufacturers were providing the full discounts that were required by the 340B law.

I was concerned when I learned late last year that HRSA was putting these manufacturer compliance provisions on hold because the agency said it lacked adequate funding.

I raised concerns, my allies in the Senate raised concerns, and your leadership raised concerns – with HRSA and with appropriators. And the budget situation was resolved. The work of all of you to more than double the funding for program administration this year means that, soon, hospitals, Community Health Centers, AIDS drug purchase programs, Ryan White clinics and family planning clinics will, for the first time, know whether the prices they receive are the correct, discounted prices.

This is an important victory.

But it is not the only area where there has been controversy within the 340B universe.

In May, a federal judge with DC District Court of Appeals ruled on a HRSA decision regarding orphan drugs in the 340B program. The ruling was that HRSA could not interpret the new orphan drug exemption in the 340B program narrowly – that the exemption had to be applied to any orphan drug even if it was used to treat a non-orphan disease.

I disagree with this decision; I know that when we added this provision to the Affordable Care Act, we intended it to be a narrow exclusion that applied only to orphan drugs when used for orphan applications. Chairman Harking and I sent a letter indicating that intent to HRSA during the rulemaking process. The exemption in the law was not intended to deprive covered entities of discounts on a significant number of drugs.

After the ruling, HRSA announced that it would be moving forward to implement the exemption narrowly through guidance rather than rulemaking. I believe this interpretation is consistent with our original intent.

I am aware that the expansion of the program has resulted in increased criticism by drug manufacturers, particularly when it comes to the expansion of contracting pharmacy arrangements.

Drug manufacturers argue that these arrangements benefit hospitals but provide no benefits for patients.

I think that this criticism misses an important point of the 340B program. It is not just a program designed to help patients. It is also a program to help safety net hospitals and covered entities generally. When participating providers pay lower costs for prescription drugs, it lowers their cost of providing care – and that means that they can provide more and better care on their limited budgets.

Hospitals and other eligible entities also need to live up to their end of the bargain: to use their 340B savings wisely and to meet community needs; to make sure that they are only obtaining 340B savings for legitimate patients; and to make certain that they are making decisions based on the best interests of those patients rather than on any financial incentives created by the 340B program.

I know that we are all waiting on HRSA rules to implement a number of key changes to the 340B program. I hope that those rules are consistent with the intent of the program, and I hope they allow you to continue your important work.

I'll continue to keep a close eye on those issues in my final months in Congress. And I hope that we have the opportunity to address one piece of unfinished legislative business. When we passed the Affordable Care Act, I tried hard to expand the 340B program to include inpatient drugs. We came close, but this provision was not included in the final legislation. Before I leave Congress, I hope that we have the opportunity to finish the job on the 340B inpatient expansion.

I thank you for the opportunity to speak and for the award today. But most importantly I thank you for the important work that you do every day to help provide health care to the medically needy.